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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,979	03/24/2004	Assaf Govari	BIO-5044	4469

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,979	GOVARI, ASSAF	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received August 11, 2009, have been fully considered by the examiner. The following is a complete response to the August 11, 2009 communication.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley (5,630,837) in view of the teaching of Moore et al (6,245,020).

Crowley discloses an acoustic ablation catheter comprising an ultrasound array (502) arranged around the longitudinal axis at the distal portion of the device. The array may operate as a phased array (see col. 4, lines 59-67) to apply ablating energy to tissue, and the phased array may be used to control the energy profile in a desired manner (column 5, lines 1-23). Also, Crowley specifically discloses the use of a reflecting shield (612 – Figure 13) to provide energy in a range of approximately 180 degrees. Thus, Crowley provides two mechanisms to control the ablation energy profile delivered to tissue: phase control to target specific areas/profiles and a reflector to limit the angular range of the delivered energy. The only feature not expressly taught by Crowley is the use of between about 32 and 64 transducers.

The particular number of transducers being used is deemed to be an obvious design consideration for the skilled artisan. Applicant's specification indicates that it is

not necessary to have between 32 and 64 transducers (see para. 0033 of the printed publication). Moreover, it is generally known to provide phased arrays having 32 elements as fairly taught by Moore et al (col. 19, lines 4-14). Moore et al also disclose a circumferentially arranged array of transducers and specifically teach the use of 32 elements.

To have provided the Crowley device with an array of 32 or more transducer elements making up the array would have been an obvious design consideration for one of ordinary skill in the art, particularly since Moore et al fairly teach that it is generally known to use an array of 32 transducers in a circumferentially arranged phased transducer array.

Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley ('837) and Moore et al ('020) as applied to claim 1 above, and further in view of Diederich et al (6,117,101).

The combination of the Moore et al teaching with the Crowley device has been addressed previously. Crowley disclose the use of mapping electrodes and ultrasound imaging for identifying tissue to be treated, but fail to specifically indicate that the array is activated in response to the determination of tissue. It is intuitive that the determination of tissue, specifically targeted tissue, would be used to control the delivery of energy so as to not treat non-targeted tissue areas.

Diederich et al disclose another catheter ablation device that may employ an ultrasound array for providing ablative energy to tissue. Diederich et al also specifically

disclose embodiments which limit or control the ablative energy to being delivered at specific azimuth ranges (col. 32, lines 52-63 as well as Figure 18a, col. 39, lines 38+). Additionally, Diederich et al teach that it is known to identify (i.e. determine) tissue and to control the energy delivery based on tissue sensing (see flowchart of Figure 9). Column 22, lines 15-22 disclose the use of a controller with the monitoring circuitry used to control ablation output based on sensed tissue conditions.

To have provided the Crowley device, as modified by the teaching of Moore et al, with a controller to control the delivery of ablation energy based on tissue sensing and identifying would have been an obvious modification for one of ordinary skill in the art, particularly since Diederich et al teach that it is known to provide such a controller to control the delivery of ablation energy based on sensed tissue in an analogous system.

Response to Arguments

Applicant's arguments filed August 11, 2009 have been fully considered but they are not persuasive.

Regarding the Crowley reference, applicant asserts that the Crowley transducers are provided in an annular configuration, and are not circumferentially arranged (bottom of page 3 to page 4 of the response). It is the examiner's position that the annular transducers may fairly be considered to be circumferentially arranged along the longitudinal axis since each transducer is clearly circumferential and the transducers are provided linearly along the longitudinal axis (as shown in Figures 1 and 2). Applicant has not defined any particular shape and/or orientation for the transducers that would preclude such an interpretation of the Crowley reference. The Crowley references are

clearly used in a phased array to treat tissue at a desired location (see, for example, Figure 6), and Crowley clearly teaches a mechanism (i.e. shield 612, Figure 13) to restrict treatment to less than 360 degrees. Thus, the only feature not expressly taught by Crowley is the specific number of transducers.

The examiner maintains that the particular number of transducers being used would be an obvious design consideration (e.g. depending on the treatment size), and that the use of phased arrays in numbers between about 32 and 64 transducers is generally known. In particular, the Moore reference is cited merely as an indication of the know use of 32 or more transducers in an array. While Moore uses the transducers for imaging, the examiner maintains that the germane teaching rests in the particular number of transducers in the array and the particular application (i.e. imaging or treatment) is immaterial. The relevant teaching remains the control afforded by an array of transducers when using a phased array numbering 32 or more to control the characteristics of the phased array.

Also, it is again noted that applicant has provided no criticality or unexpected result associated with the use of between 32 and 64 transducers in the array. While applicant asserts on page 5 of the response that “remarkable unexpected results” are achieved, there is no evidence of any criticality or unexpectedness in the specification. That is, while applicant may disclose a preferential energy distribution, there is no reason that one of ordinary skill in the art would not be expected to determine similar results through routine experimentation. There is simply no suggestion that the use of any particular number of transducers would result in an energy profile that could not be

ascertained through routine experimentation. Crowley clearly teaches a phased array of transducers for creating desired energy profiles to treat tissue, and also clearly teach the use of a mechanism to limit the application of the energy profile to less than 360 degrees (figure 13). The examiner continues to maintain the specific number of transducers is an obvious design consideration, particularly considering Moore's teaching of the use of 32 or more transducers in a phased array.

Applicant's arguments with respect to the addition of the Diederich reference are also not persuasive. The examiner maintains that Diederich clearly teaches the use of annular transducers to deliver ultrasound energy to specific azimuth ranges. One of ordinary skill in the art would obviously recognize that such a design may be employed in the Crowley device to limit the azimuth range of treatment (a desired effect as taught by Crowley with reference to Figure 13). It is noted that Crowley provides annular transducers very similar to Diederich, and Diederich teach that such transducers may be divided into sectors to control the direction of the energy profile. Again, the specific number of transducers is still deemed an obvious design consideration for the reasons expressed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
October 31, 2009